UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

CHRISTINE JANKOWSKI, et al., Plaintiffs, v. ZYDUS PHARMACEUTICALS USA, INC.; and DOES 1-50, Inclusive, Defendants.	Case No.: No. 3:20-cv-02458

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

This Court should deny the motion to dismiss. The Second Amended Complaint ("SAC") alleges in detail how Defendant, Zydus Pharmaceuticals USA, Inc. ("Zydus" or "Defendant"), violated its state-law duty to adequately warn of the dangers and complications associated with Amiodarone by failing to communicate FDA warnings to doctors. A state trial court in an Amiodarone case just recently rejected a motion for summary judgment making arguments almost identical to Defendant's arguments in this case. *Walsh v. Upsher-Smith Labs., Inc.*, 2021 Minn. Dist. LEXIS 430, *19 (Oct. 4, 2021).

Defendant first argues that Plaintiffs' negligence claims are subsumed by the New Jersey Products Liability Act. But Plaintiffs expressly pleaded their negligence claims *in the alternative* if this Court finds that the law of their home states applies. The Federal Rules of Civil Procedure expressly permit alternative pleading. In all the cases Defendant cites, it was apparently undisputed that New Jersey law applied. This issue appears to be a moot point, however, because Defendant does not appear to dispute that New Jersey substantive law applies.

Defendant next argues that it had no duty to communicate FDA warnings to doctors, so Plaintiffs' failure-to-warn claims are inadequately pleaded. Essentially, Defendant contends that it has no duty to warn consumers and that the mere existence of an adequate warning is sufficient to warn doctors. Defendant's

argument fails. Contrary to Defendant's assertion, many courts—including a court this October in a related Amiodarone case—have held that manufacturers must communicate FDA warnings to physicians. That is, the mere existence of an adequate warning is not sufficient. Indeed, it appears that most courts require manufacturers *at least* to place their FDA warnings in the Physician's Desk Reference ("PDR"), which Zydus did not do.

This rule makes much more sense than the minority rule because package inserts are not intended to go to doctors and, in any event, the pharmacist usually discards package inserts. In other words, Defendant asks this Court to hold as a matter of law that a warning that is almost certain *not* to reach doctors is sufficient to warn doctors as a matter of law. This is not a case in which the doctors testified that they never read any product information. Doctors have not testified at all. In fact, Plaintiffs pleaded that, in the vacuum created by Defendant's failure to provide FDA warnings, doctors relied on misleading information in third-party sources that falsely suggested Amiodarone was safe to prescribe for atrial fibrillation.

Next, Defendant argues that Plaintiffs' claims are preempted, because it is "impossible" for Defendant to comply with state law requiring it to communicate adequate warnings to physicians. But Plaintiffs argue that Defendant is liable for failing to communicate the *FDA warning*. Plaintiffs do not allege that Defendant should have changed the FDA warning at all. Federal law allows Defendant to

communicate warnings if the warnings are the same as the warning approved by the FDA. Federal law certainly does not forbid Defendant from warning doctors by, for instance, submitting FDA warnings for publication in the PDR.

This Court should disregard Defendant's arguments directed toward Plaintiffs' Medication Guide or fraud theories. Although Plaintiffs preserved these theories for appeal, the Court dismissed them, and the Second Amended Complaint does not rely on them.

Finally, Plaintiffs' claims are adequately pleaded, and none of them is barred by the New Jersey statute of limitations. And while many Plaintiffs did file initially in California, their claims were dismissed for lack of personal jurisdiction, leading Plaintiffs to file suit in the manufacturers' home states. There was nothing improper about this, and Plaintiffs recognize they cannot obtain a double recovery. Accordingly, because Defendant has raised no basis to dismiss Plaintiffs' claims, this Court should deny its motion to dismiss.

SUMMARY OF FACTUAL ALLEGATIONS

Plaintiffs are 220 individuals who either ingested the drug Amiodarone or are the family members of individuals who died from or were injured by Amiodarone. Plaintiffs or their decedents were diagnosed with a-fib. SAC ¶¶ 1-153 (in subparagraph a). In the Second Amended Complaint, Plaintiffs alleged personal injury based on Defendant's failure to warn when it failed to communicate FDA-

mandated warnings to Plaintiffs' physicians. *See id.* ¶¶ 1-153 (in subparagraph b, d, e, and g).[1] Their doctors, because of Defendant's failure to warn, prescribed Amiodarone that Defendant manufactured. *Id.* ¶¶ 1-153 (in subparagraph d). Plaintiffs filled the prescriptions. *Id.* Because they took Amiodarone, they or their decedents experienced serious side effects. *Id.* ¶¶ 1-153 (in subparagraph g).

Amiodarone is the generic form of the Wyeth-branded drug Cordarone®. SAC ¶¶ 1-153 (in subparagraph e), 166. Zydus manufactures the generic version and received FDA approval to manufacture, market, and sell Amiodarone under an alternate new drug application that was based on the same requirements and limitations as the brand name drug, Cordarone. *See id.* ¶¶ 1-153(in subparagraph e). 166. As a result, Zydus' generic version of Amiodarone could be legally sold only for the same limited uses. But the FDA approved Cordarone® for use in the United States in 1985 only for treating life-threatening recurrent ventricular fibrillation or hemodynamically unstable ventricular tachycardia—and, even in those cases, only as a drug of last resort. *Id.* ¶¶ 157, 166, 177-78. It has never been approved for the treatment of atrial fibrillation and is unreasonably dangerous for such a use, even though each of the Plaintiffs or their decedents filled it for that use. *See id.* ¶¶ 1-153 (in subparagraph b).

[1] Plaintiffs alleged additional claims and theories—which this Court dismissed—in their previous complaints. Plaintiffs expressly reserved these claims for appeal. SAC ¶ 187 n. 24.

ARGUMENT

I. Plaintiffs Sufficiently Alleged Claims Under New Jersey Law.

Defendant argues that Plaintiffs' causes of action for negligence are barred under New Jersey law, because the NJPLA subsumes their claims. This objection is misplaced, however, because Plaintiffs specifically alleged these causes of action in the alternative if "this Court holds that the law of Plaintiffs' home states," rather than New Jersey law, "applies." SAC ¶ 199.

The Federal Rules of Civil Procedure expressly provide that a plaintiff may "set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones." FED. R. CIV. P. 8(d)(2). "If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient." *Id.* In other words, "Plaintiff is permitted to plead alternative theories of recovery." *MSKP Oak Grove, LLC v. Venuto*, 875 F. Supp. 2d 426, 442 (D.N.J. 2012). The cases cited by Defendant all involve situations in which it was apparently undisputed or established that New Jersey substantive law applies.

Here, Plaintiffs pleaded the law of their home states in the alternative, not as additional claims. If New Jersey law applies, then Plaintiffs agree that their negligence claims are subsumed. But if the law of Plaintiffs' home states applies, then Plaintiffs' claims cannot be subsumed by New Jersey law. This is a moot point, however, because apparently both sides agree that New Jersey law applies.

II. Plaintiffs' Sole Live Theory[2]—That Defendant Failed to Communicate Adequate Warnings to Plaintiffs' Doctors—is Not Barred.

A. Plaintiffs' Claims Were Adequately Pleaded.

Plaintiffs alleged that Defendant failed to warn by failing to communicate FDA warnings to Plaintiffs' doctors. Under New Jersey law, a manufacturer is liable for failure-to-warn unless a "product contains an adequate warning or instruction." N.J. STAT. § 2A:58C-4. Here, the product did not "contain" an adequate warning, because the prescriptions Plaintiffs filled were not accompanied by FDA labeling information, and—more importantly, since most prescription drug warnings are intended for physicians and Plaintiffs alleged failure to warn their doctors—Defendant did not communicate FDA warnings to Plaintiffs' doctors. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g). For instance, Zydus did not place the FDA warnings in the PDR during the relevant period. SAC ¶ 169. In fact, there were *no* package inserts for *any* form of Amiodarone in the PDR from 2008 to 2016, the period during which most Plaintiffs were first prescribed Zydus Amiodarone (Zydus concedes in its brief that it did not even start manufacturing Amiodarone until 2008).

Because they did not receive *any* warnings, Plaintiffs' doctors falsely believed that Amiodarone was safe and effective as a first-line treatment for atrial fibrillation.

[2] Plaintiffs expressly preserved their other claims for appeal.

If the doctors had received FDA warnings,[3] they would not have prescribed Amiodarone. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g).

Defendant contends that it satisfied its duty to warn as a matter of law because its labeling containing the FDA warnings was presumably affixed to bottles shipped to pharmacies—even though doctors do not receive labeling attached to prescriptions, and pharmacists generally throw it away. It provides no evidence or even argument that there were sufficient labels to accompany each prescription of Amiodarone consumed by Plaintiffs. (Based on Plaintiffs' experience in other Amiodarone cases, each bottle contains more than one prescription.) Essentially, then, Defendant points to the mere existence of the labeling.

Contrary to Defendant's assertion, many courts have held that a drug manufacturer can be liable if it fails to communicate FDA warnings to doctors. Defendant failed use a method of warning that "gives a reasonable assurance that the information will reach" physicians. RESTATEMENT (SECOND) OF TORTS, § 388. Just a couple months ago in an Amiodarone case, a court denied a motion for summary judgment in which the defendant made arguments just like the arguments Defendant makes here. *Walsh v. Upsher-Smith Labs., Inc.*, 2021 Minn. Dist. LEXIS 430, *7 (Oct. 4, 2021). In that case, "[b]oth sides agree[d] that the substance of the

[3] Under New Jersey law, the FDA warning, which Defendant did not provide in this case, is rebuttably presumed to be adequate.

FDA-prescribed set of warnings for Amiodarone is adequate." *Id.* But the "Plaintiffs alleged that [the manufacturer] had failed to communicate FDA warnings to Plaintiffs' doctors, leading them to form a false belief that Amiodarone was safe and effective as a first-line treatment for atrial fibrillation." *Id.* at *7-*8.

The defendant, however, argued that "it cannot be disputed that the FDA-prescribed warnings were provided to physicians." *Id.* It asserted, like Defendant here, that the warning was available in many places. For instance, it was available on a "government website, [the manufacturer's] own websites, and various online publications." *Id.* at *8. The manufacturer also included "a package insert with each bottle of Amiodarone" (not each prescription) and "[f]or some number of years, prescribing information for Amiodarone was available in the [PDR]." *Id.*

The *Walsh* plaintiffs pointed out that the manufacturer had provided no evidence that any of the plaintiffs' doctors had actually received the FDA warnings. *Id.* And like New Jersey law, "under Minnesota law, generally, the adequacy of a warning is a fact question for the jury." *Id.* (quotation omitted). They argued that the "law allows a reasonable jury to determine whether a pharmaceutical company's method of communicating FDA warnings was sufficient, when a plaintiff provides evidence that 'the package insert and PDR warnings were not adequately communicating the [FDA warnings] to physicians.'" *Id.* *9 (quoting *Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, 700 F.3d 1161, 1167 (8th Cir. 2012)).

The court agreed with the plaintiffs that "genuine issues of material fact exist regarding the adequacy of [defendant's] method of communicating FDA warnings to physicians." *Id.* Although the "FDA warning expressly states that Amiodarone should only be prescribed for life-threatening ventricular arrhythmias[,]" there was "evidence that a majority of Amiodarone prescriptions were being used to treat atrial fibrillation[,]" which could "be construed as circumstantial evidence of the ineffectiveness of [defendant's] methods of warning physicians about the dangers of such prescriptions." *Id.* at *11. In the absence of any evidence that the Plaintiffs' physicians received the FDA warnings, the court could not "find, as a matter of law, that [the manufacturer] satisfied its duty to warn Plaintiffs' physicians." *Id.* This was especially true since the manufacturer did not place its warning in the PDR when it could have or provide "the warnings directly to physicians or publish[] them in other publications likely to be read by prescribing physicians." *Id.* at *12.

Here, there is even less reason to grant Defendant's motion to dismiss. While the *Walsh* court was ruling on a motion for summary judgment, Defendant has moved to dismiss. "A motion to dismiss under Rule 12(b)(6) for failure to state a claim upon which relief can be granted does not attack the merits of the case, but merely tests the legal sufficiency of the Complaint." *Video Pipeline, Inc. v. Buena Vista Home Entm't, Inc.*, 210 F. Supp. 2d 552, 556 (D.N.J. 2002). Thus, "[w]hen considering a Rule 12(b)(6) motion, the reviewing court must accept as true all well-

pleaded allegations in the Complaint and view them in the light most favorable to the plaintiff." *Id.* There is no evidence in the record that the FDA labeling "accompanied" the prescriptions that Plaintiffs filled. And, regardless, the FDA labeling (except for the Medication Guides, which Plaintiffs also did not receive) is supposed to go to doctors, not to consumers, and Plaintiffs pleaded that their doctors did not receive it. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g).

Plaintiffs in this case alleged under the NJPLA that Defendant did not communicate FDA warnings to their doctors and that, as a result, their doctors falsely believed that Amiodarone was safe to prescribe for atrial fibrillation because they were forced to rely on misleading information in other sources. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g), 169, 172, 176. Plaintiffs specifically pleaded that Zydus has never placed the FDA warning in the PDR and did not otherwise take adequate measures to communicate warnings to doctors. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g), 169.

Defendant implies that it satisfied its duty to warn as a matter of law because an adequate warning is accessible on a government website and can be found in package inserts.[4] In essence, Defendant contends it has no duties at all. It has no duty to warn consumers, because its duty to warn runs only to the physician. And it has

[4] Defendant, again, does not actually attempt to prove that the package inserts were included with Plaintiffs' prescriptions.

no duty to communicate FDA warnings to the doctor, because doctors know how to find warnings. The problem with Amiodarone, though, is that doctors do not, in fact, know that Amiodarone is unsafe to prescribe for non-life-threatening atrial fibrillation. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g), 169. For this reason, it is especially important that Amiodarone manufacturers take reasonable steps to communicate FDA warnings to physicians.

In arguing that the mere existence of a package insert satisfies the requirement of warning the doctor as a matter of law, Defendant ignores that "[t]he pharmacist … often removes and discards the insert …. *There is no system for insuring, or even making it likely, that the physician sees the insert*." *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 406 (N.Y. App. Div. 1979) (emphasis added); *see also Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 662 (Cal. 1973) ("Many prescribing physicians would not come into contact with package inserts or warning labels attached to the drug when the pharmacist filed the prescription. … It was within reason for the jury to find such warnings inadequate and to hold Parke, Davis liable for failing to reasonably warn of the drug's danger."); *see also Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 (Minn. 1970) ("[P]laintiff alleges the company was negligent in putting a dangerous drug on the market without giving adequate warning as to its use. . . . Although 'stuffers' which accompanied [the medication] and the so-called physicians' desk reference gave adequate warning, plaintiff claims they did not come

to the doctor's attention.").

The *Baker* court explains why the mere existence of an adequate warning is insufficient. 70 A.D.2d at 402-03. The *Baker* plaintiff alleged failure to warn against a drug manufacturer after the drug Dicumarol injured her fetus. *Id.* The FDA warning specifically warned against prescribing Dicumarol to pregnant women. *Id.* at 402. "The statement of contraindication appeared in [the manufacturer's] package inserts at the time the instant cause of action arose." *Id.* And "[a]s an additional measure, [the manufacturer], for a time, published information on Dicumarol in the [PDR], the compendium often relied upon by physicians to obtain knowledge of the proper uses and hazards of drugs." *Id.* But later, the manufacturer "inexplicably withdrew its PDR statement entirely." *Id.* at 403.

The doctor, for his part, "did not consult the package insert or any other source of information on Dicumarol before ordering it for" the plaintiff. *Id.* at 403. "Based upon [the doctor's] testimony and upon the contents of its own package inserts, [the manufacturer] moved for summary judgment dismissing the complaint … against it." *Id.* When the trial court denied summary judgment, the manufacturer appealed.

The appellate court affirmed the denial of the summary judgment. It first explained that the patient—especially in the absence of a plain English Medication Guide—must rely on the doctor to get information about the drug. *Id.* at 405. But "even the physician upon whom the patient most directly relies may himself lack a

complete knowledge of the potential hazards of each of the myriad of drugs at his disposal." *Id.* Although "[s]tandards of competent medical care require the physician to obtain such knowledge before administering the drug, … he likewise must rely on others to provide the information in the first instance." *Id.* Thus, it is "well established that a drug manufacturer is under a duty to warn the medical profession of dangers inherent in its biological drugs which, in the exercise of reasonable care, it knew or should have known to exist." *Id.* (internal quotation omitted).

In the *Baker* case, as here, the "plaintiffs themselves concede[d] that [the manufacturer's] package insert warning was adequate, wholly proper and precisely that which is required." *Id.* at 406. But, the court explained, this cannot end the inquiry, because "no matter how detailed and accurate, an uncommunicated warning is no warning at all." *Id.* So, the drug manufacturer must maintain adequate warnings for its products. *Id.* But "equally important, it must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." *Id.* (citing cases and literature). "The greater the potential hazard of the drug, the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession." *Id.*

The manufacturer in *Baker*, like Zydus here, failed to fulfill that second aspect of its duty. Plaintiffs acknowledge that, because of its duty of sameness, Zydus was not at liberty to change the language of the FDA warning. But its duty of sameness

did not prevent it from taking other measures to warn. In *Baker*, the court pointed out that the package insert does not reach and is not even intended to reach the doctor. First, the pharmacist usually throws it away. *Id.* Second, even if it was included with the prescription,[5] the patient would receive it, not the doctor for whom it is intended. *See id.* The court noted that "[t]here are other, well-known methods by which pharmaceutical manufacturers apprise the medical profession of the dangers of a drug." *Id.* at 407. "One is the PDR[.]" *Id.* "Others include so-called 'Dear Doctor' letters addressed to physicians, notices in medical journals, and the use of 'detail men' who call upon physicians personally to present them with information concerning pharmaceuticals." *Id.* The manufacturer, like Zydus in this case, used none of these methods.

The court pointed out that this was a different situation from a case in which the doctor simply ignored adequate warnings that he received. *See id.* ("This is not a case where the physician deliberately disregards the manufacturer's warning in favor of his own supposed knowledge of the drug."); *c.f. Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 62 (N.Y. App. Div. 1979) ("We consider *Baker* distinguishable since in that case the warnings were furnished at one time in the [PDR] and then later discontinued. In the instant case not only were the warnings fully descriptive and

[5] Here, of course, Plaintiffs specifically pleaded that they did not receive the package insert intended for patients called a "Medication Guide." SAC ¶ 179.

complete, but *they were communicated to the prescribing physician*") (emphasis added). In *Baker*, as here, "the physician's failure to search the literature can hardly be described as an unforeseeable circumstance." *Id.* That is especially the case here when, because of misleading marketing, physicians routinely prescribe Amiodarone for non-life-threatening atrial fibrillation because they are unaware of the FDA labeling. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g). The *Baker* court concluded that "the adequacy of [the manufacturer's] warnings presents a question of fact to be determined at trial." *Id.* at 408.

This case is very similar to *Baker*. Here, Plaintiffs pleaded that Amiodarone is an extremely dangerous drug, which causes severe lung disease—fatal 10% of the time—in up to 17% of people who take it. *See* SAC ¶ 180. Plaintiffs' physicians were unaware of the extent of the dangers of Amiodarone because Defendant did not communicate FDA warnings to them, so they relied on unreliable sources. SAC ¶¶ 1-153 (in subparagraph b, d, e, and g), 193. Defendant did not even submit its labeling to the PDR—something that it is permitted to do under federal law and that is essential to an adequate warning under New Jersey law. SAC ¶ 169. If Defendant had communicated the FDA warning to Plaintiffs' doctors, they would not have prescribed Amiodarone for Plaintiffs' non-life-threatening a-fib.

Defendant cites several cases in which the doctor received the FDA labeling but did not read it or testified that he would not have read the warning even if he had

received it or that an adequate warning would not have changed his prescribing decision. *See, e.g.*, *Seavey v. Globus Med., Inc.*, No. CIV. 11-2240 RBK/JS, 2014 WL 1876957, at *10 (D.N.J. Mar. 11, 2014) ("In the case of certain prescription drugs and medical devices, a manufacturer satisfies its duty to warn by *providing the prescribing physician* with information about the dangers of the drug or device.") (emphasis added); *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (holding on full evidentiary record that plaintiff could not show that "an alleged failure to warn was the proximate cause of his injuries" when the evidence showed that his doctor knew about the risks of the drug described in the labeling); *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 968 (S.D. Tex. 2012) (focusing on whether a warning's *language* was adequate).

One of the cases Defendant cites is *Alston*. The *Alston* court cited *Wolfgruber* for the proposition that "[i]t has long been the law in New York that prescription medicine warnings are adequate when, as here, information regarding the precise malady incurred was communicated in the prescribing information." *Alston*, 670 F. Supp. 2d at 284. Crucially, though, *Wolgruber*, far from overruling *Baker*, distinguished it by noting that, in *Baker*, as here, the manufacturer failed to communicate the FDA warnings in the PDR. *Wolfgruber*, 72 A.D.2d at 62.

Defendant's citation to New Jersey law is misleading. *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245, 1261 (N.J. 1999). Defendant quotes *Perez* as

stating that "a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine if the prescribing physician . . . did not read the warning at all." MTD at p. 17. Defendant fails to note, however, that this passage was quoting another source, which was discussing the "superseding cause" principle. *See Perez*, 734 A.2d at 1261 (quoting Richard J. Heafey & Don M. Kennedy, *Products Liability: Winning Strategies and Techniques* § 10.03 (1999)). After quoting this source, the New Jersey Supreme Court specifically rejected its application: "On balance, we believe that the patient's interest in reliable information predominates over a policy interest that would insulate manufacturers." *Id.* at 1262. It explained that "[p]roducts liability law is based on concepts of fairness, feasibility, practicality and functional responsibility. We have always stressed the public's interest in motivating individuals and commercial entities to invest in safety to protect workers." *Id.* (quoting *Zaza v. Marquess and Nell, Inc.*, 675 A.2d 620 (N.J. 1996)).

Defendant also cites *dicta* from *Hrymoc v. Ethicon, Inc.*, 249 A.3d 191 (Super. Ct. App. Div. 2021). But in fact, the *Hrymoc* decision supports Plaintiffs' position overall. The *Hrymoc* court explained that "[p]atients deprived of reliable medical information may 'establish that the misinformation was *a substantial factor contributing to their* use of a defective pharmaceutical product.'" *Hrymoc*, 249 A.3d at 217. Quoting a "leading treatise" approvingly, it explained that

> Where the plaintiffs' prescribing physicians *unequivocally* testify that they had full knowledge of the dangers associated with a drug and that neither that knowledge nor anything in the enhanced post-injury warnings supplied by the manufacturer would have altered their decision to prescribe it, the plaintiff has failed to show that inadequate warnings are a proximate cause of injury and there must be a verdict for defendant.

Id. at 220 (quoting Dreier, Karg, Keefe & Katz, *N.J. Products Liability & Toxic Torts Law* § 8:3-2 at 203 (2020)) (emphasis added by court). But "[w]here such a statement is not unequivocal the matter is properly for the jury." *Id.*

Here, Zydus provided no warnings *to the physicians*. This is not a case where the physicians testified that they read no warnings at all or that a proper warning would not have changed their recommendation. The physicians have not testified yet at all. And Plaintiffs pleaded that (1) in the absence of FDA warnings, the doctors were forced to rely on misleading third-party sources (SAC ¶ 176) and (2) if Plaintiffs' doctors had received FDA warnings, they would have read them and would not have prescribed Amiodarone (SAC ¶¶ 1-153 (in subparagraphs b-d)). If Defendant had communicated the FDA warning, Plaintiffs' doctors would have heeded them. SAC ¶¶ 1-153 (in subparagraphs d). In other words, Plaintiffs' doctors *did* read the only "warnings" they got, which were not the FDA warnings. In the vacuum created by Defendant's inaction, the doctors relied on misleading information not approved by the FDA.

Defendant's interpretation of New Jersey law creates a Catch-22 such that a

defendant manufacturer can always avoid liability simply by not providing a warning. After all, if the physician never receives a warning, there is nothing for her to read. And, Defendant reasons, if the doctor does not read anything, the manufacturer's failure to provide anything to read cannot be the cause of the consumer's injuries. Defendant's reasoning only makes sense in failure-to-warn cases in which a plaintiff complains that a manufacturer communicated an inadequate warning. Here, Plaintiffs complain Defendant communicated nothing.

Defendant's reference to *Harris v. McNeil Pharm.*, No. 3:98cv105, 2000 U.S. Dist. LEXIS 22972 (D.N.D. 2000) is similarly unavailing. In that case, the plaintiff *was* a physician and failed to read the package insert and the PDR. *Harris*, 2000 U.S. Dist. LEXIS 22972, at *10. Here, though, Plaintiffs pleaded that Defendant never communicated the FDA warning to their doctors, either through the package insert (which doctors generally do not receive) or through the PDR. Reading the PDR would not have helped, because Zydus did not place FDA warnings for Amiodarone in the PDR *See Pettit v. SmithKline Beecham Corp.*, 2012 Phila. Ct. Com. Pl. LEXIS 214, *10 (June 12, 2012) ("[The prescriber] repeatedly testified he could not recall ever reviewing the [drug's] label *or* [*the PDR*].") (emphasis added).

Though Defendant cites some out-of-state decisions that seem to support its position, most states require manufacturers to warn *at least by placing warnings in the PDR*, especially when, as here, Plaintiffs allege physicians are not receiving FDA

warnings. *Schedin*, 700 F.3d at 1167. The *Schedin* court explained that "[m]any courts considering the question have held a properly worded package insert is a sufficient warning as a matter of law, *at least when it is combined with an entry in the PDR*." *Id.* (emphasis added). On the other hand, other courts hold that even the PDR is not necessarily sufficient. *See id.* The *Schedin* court ultimately held that, even if the PDR and package insert are usually sufficient, they are not sufficient if there is evidence doctors are not receiving the FDA warnings. *Id.* at 1167 ("[A] reasonable jury could find [the manufacturer] should have realized the adverse event reports indicated physicians were unaware of the [relevant FDA] warning").

Here, Defendant's warning was insufficient regardless of which side of the split discussed in *Schedin* the Court accepts. Defendant did not warn about its Amiodarone in the PDR during the relevant period when Plaintiffs were first prescribed Defendant's Amiodarone. SAC ¶ 169. And there is evidence that doctors are not receiving the FDA warnings, because they continue to prescribe Amiodarone for non-life-threatening atrial fibrillation, even though the FDA labeling warns against this use. *See* SAC ¶¶ 1-153 (in subparagraph b, d, e, and g), 193. It is true that there are some states that seem to imply that the mere existence of a package insert constitutes a sufficient warning. *See Sherman v. Pfizer, Inc.*, 440 P.3d 1016, 1024-25 (Wash. Ct. App. 2019). But this minority position makes no sense because doctors do not actually receive package inserts.

Finally, Defendant argues that it adequately warned because its warning is available on third-party websites. *See* MTD at p. 19 ("[A]ny allegation that Zydus did not make their label available is unsupported by any facts. Zydus' label has been published on federally run websites like Dailymed for the last decade."). This argument is bizarre, given Zydus's insistence that it cannot be liable for misinformation in third-party sources. Zydus apparently wants to disclaim any responsibility for misinformation on third-party websites but take credit for FDA-approved information on third-party websites. This Court should not let Zydus have it both ways.

Defendant also suggests vaguely that Plaintiffs' Second Amended Complaint is inadequately pleaded under FED. R. CIV. P. 8 because it contains minor drafting errors. For instance, Plaintiff pleaded that Cecil Thomas received 400 mg tablets of Amiodarone, even though Zydus only manufactures 200 mg tablets. MTD at p. 33. Plaintiffs reviewed the prescription records, and it appears that Mr. Thomas was prescribed 400 mg tablets at one point and tapered down to 200 mg tablets. But he filled the 400 mg prescription with two 200 mg tablets.

As another example, Zydus states that some Plaintiffs claim to have been prescribed Amiodarone as far back as 2000, before it received FDA approval to market Amiodarone. MTD at p. 33. But many Plaintiffs consumed Amiodarone from multiple manufacturers. Defendant will learn details in discovery, but Plaintiffs do

not object to repleading to correct these minor drafting errors or clarify ambiguities. The core of Plaintiffs' claims is clear.

Because Defendant failed to communicate FDA warnings to Plaintiffs' physicians, Defendant failed to adequately warn. Accordingly, this Court should deny Defendant's motion to dismiss.

B. Plaintiffs' Claim is Not Preempted.

Defendant contends that, as a generic manufacturer, it is not allowed to communicate FDA labeling to doctors under federal law. In other words, Defendant argues it would violate federal law for it to communicate federally mandated physician warnings to physicians.

Defendant's argument is based on a misreading of the primary case it cites, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, the Court explained that a "Dear Doctor letter *that contained substantial new warning information* would not be consistent with the drug's approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent *such letters* [*i.e.*, Dear Doctor letters containing substantial new warning information], that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* at 615 (emphasis added).

In contrast to *Mensing,* Plaintiffs here merely want Zydus to communicate the FDA-mandated labeling, not "substantial new warning information." *Id.* Plaintiffs

have always acknowledged that, under *Mensing*, all labeling information Defendant provides must be the same as the brand labeling. Regardless, even if Defendant cannot send out Dear Doctor letters containing the FDA-mandated labeling, it does not contest that it has other methods of communicating warning—for instance, the PDR. In *Schedin*, the court explained that "drug companies communicate with physicians about their products using the PDR, in-person visits by sales representatives, 'Dear Doctor' letters sent to individual physicians, and other methods." 700 F.3d at 1164. Zydus does not argue that its federal duties preclude all methods of warning physicians.

Because it was not "impossible" for Zydus to communicate FDA warnings to Plaintiffs' physicians, Plaintiffs' claims are not preempted.

III. Plaintiffs Did Not Allege Their Medication Guide or Fraud Claims in the Second Amended Complaint.

Defendant spends a large portion of its motion to dismiss contending that Plaintiffs' fraud and Medication Guide claims are inadequately pleaded and must be dismissed as preempted. *See* MTD at pp. 20-24, 29-32, 33-36. For the reasons set forth in their response to Defendant's original motion to dismiss, Plaintiffs disagree on the substance. But this Court has already dismissed Plaintiffs' Medication Guide theory and fraud claims. And while Plaintiffs expressly preserved these claims for appeal, Plaintiffs do not urge them in their SAC. SAC ¶¶ 187 n. 24, 188-96.

Defendant points to two paragraphs in the live complaint that reference

Medication Guides, but neither paragraph asserted a Medication Guide claim. MTD at p. 5 (citing SAC ¶¶ 167, 191). In ¶ 167, Plaintiffs mention Defendant's duty to provide Medication Guides only as background information. SAC ¶ 167. In ¶ 191, Plaintiffs do not even mention Medication Guides. Instead, they note that, because Plaintiffs never received any information from Defendant, Plaintiffs did not know the potential risks and side effects of Amiodarone. SAC ¶ 191. Even if Defendant only had a duty to warn doctors (as Plaintiffs have consistently alleged that it failed to do), the information in ¶ 191 is obviously relevant to causation.

Because Plaintiffs did not allege a Medication Guide theory or a fraud claim in their Second Amended Complaint, Defendant's argument directed at these theories is misplaced.

IV. The Statute of Limitations Does Not Facially Bar Plaintiffs' Claims.

None of the Plaintiffs' claims is facially barred by the statute of limitations. All the Plaintiffs pleaded tolling doctrines and that their claims did not accrue until well after they consumed Amiodarone. SAC ¶¶ 1-153 (in subparagraph g). And most of the Plaintiffs that Defendant asserts are time-barred timely filed suit in California first. Because they diligently pursued their remedies in New Jersey after their California claims were dismissed for lack of personal jurisdiction and invoke other tolling doctrines, Plaintiffs' claims are timely.

Ordinarily, courts in the Third Circuit only dismiss a claim under the statute

of limitations at the motion-to-dismiss state if the claim is facially untimely. *Wisiewski v. Fisher*, 857 F. 3d 152, 157 (3d Cir. 2017) (noting that a "complaint is subject to dismissal for failure to state a claim on statute of limitations grounds only when the statute of limitations defense is apparent on the face of the complaint."). Here, Plaintiffs specifically invoke multiple tolling doctrines and did not plead the date on which their claims accrued, which prevents the statutes of limitations from running on the face of the complaint. SAC ¶¶ 1-153 (in subparagraph g) (stating that the plaintiffs learned only *later* that Amiodarone caused their injuries); 190-91; *Ben Elazar v. Macrietta Cleaners, Inc.*, 165 A.3d 758, 764 (N.J. 2017) (discussing the New Jersey discovery rule).

New Jersey has a generous tolling doctrine for claims timely filed in other jurisdictions that were dismissed due to lack of personal jurisdiction. *Mitzner v. W. Ridgelawn Cemetery, Inc.*, 709 A.2d 825, 826 (N.J. Super. Ct. App. Div. 1998). In *Mitzner*, the New Jersey court of appeals considered almost exactly this issue:

> [M]ay the two-year statute of limitations for personal injury actions, . . . be tolled by the filing of a complaint in a court of another state when the "untimely" New Jersey action is filed after the first action has been dismissed for lack of personal jurisdiction but before the time to appeal from the order of dismissal has expired[?]

Id. The court answered the question "Yes." *Id.* Relying on "New Jersey's frequent reference to equitable principles to relieve the harshness of statutes of limitations," the court held that "tolling does not end before the time to appeal has expired."

Mitzner, 709 A.2d at 828; *see also Island Insteel Sys. v. Waters*, 296 F.3d 200, 217 (3d Cir. 2002) (holding that the *Mitzner* rule—permitting tolling when a first-filed action is dismissed for lack of personal jurisdiction—is "the sounder rule" and applying it to the Virgin Islands).

The *Mitzner* court did not address whether tolling would continue after the time to appeal expired, but New Jersey courts have continued to apply the principles contained in *Mitzner*. *See, e.g.*, *Berke v. Buckley Broad. Corp.*, 821 A.2d 118, 127 (N.J. Super. Ct. App. Div. 2003). In *Berke*, the plaintiffs filed suit in New Jersey state court seventeen months after their claim was dismissed in federal court. 821 A.2d at 126. The plaintiffs had appealed to the Third Circuit, but the Third Circuit dismissed their appeal as untimely due to a technicality. *Id.* The parties did not dispute that a "timely" appeal would have saved the plaintiffs' New Jersey state action. *Id.* Under these circumstances, the court of appeals held that the statute of limitations was tolled, because the plaintiffs "diligently pursued" their remedy in another court. *Id.* at 127. The court also excused a "ten-week delay between the Third Circuit dismissal and the state filing," because the delay was "not inordinate," and the defendants could point to little prejudice as a result of the delay. *Id.*

Here, Plaintiffs diligently pursued their remedy in a New Jersey forum after their claims were dismissed for lack of jurisdiction in California. Under New Jersey tolling law, then, Plaintiffs' claims are timely filed.

Despite arguing that Plaintiffs' negligence claims must be dismissed as subsumed under New Jersey law, Defendant seems to *assume* that the statutes of limitations of Plaintiffs' home states apply. In fact, assuming *arguendo* that Plaintiffs' claims would be dismissed under the statutes of limitations of their home states, there is a "outcome determinative" conflict between New Jersey law and the law of Plaintiffs' home states. *Fairfax Fin. Holdings Ltd. v. S.A.C. Capital Mgmt., L.L.C.*, 450 N.J. Super. 1, 60, 160 A.3d 44, 79 (Super. Ct. App. Div. 2017).

Under New Jersey choice-of-law rules, which apply in this New Jersey case, "when New Jersey has a substantial interest in the litigation and is the forum state, it will generally apply its statute of limitations." *Id.* (internal quotation omitted).

> Stated another way, under [New Jersey law], the forum state "presumptively applies its own statute of limitations unless . . . [it] has no significant interest in the maintenance of the claim and the other state, whose statute has expired, has 'a more significant relationship to the parties and the occurrence,' . . . or . . . given 'the exceptional circumstances of the case,' following the Second Restatement rule would lead to an unreasonable result."

Id. (quoting *McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207, 224 (N.J. 2017)). And "New Jersey has a substantial interest in deterring its manufacturers from developing, making, and distributing unsafe products, including inadequately labeled prescription drugs." *Id.*

Therefore, in this case, the New Jersey statute of limitations and New Jersey's tolling doctrines apply in this case. Defendant does not even attempt to explain why

New Jersey substantive law would apply to bar Plaintiffs' negligence claims, but New Jersey tolling doctrine would not apply. For the reasons described above, the Plaintiffs' claims are not barred by the statute of limitations.

V. Plaintiffs Did Not File Duplicative Lawsuits Against Zydus, and, Because of Zydus and Other Manufacturers' Actions in California, it is Not "Feasible" to Sue All the Manufacturers in One Forum.

This Court should reject Zydus' novel argument that it is somehow improper for Plaintiffs to sue Zydus in its home state and other manufacturers in *their* home states. Multiple manufacturers are responsible for causing these Plaintiffs' injuries, but Plaintiffs cannot sue all of the manufacturers in the same state because there is no state where Plaintiffs could obtain jurisdiction over all of them.

With no citation to authority, Defendant asserts that, "[f]rom time to time in pharmaceutical mass tort and multidistrict litigation, some plaintiffs have either inadvertently or intentionally filed duplicative lawsuits asserting the same injury. These duplicative filings are generally not allowed to proceed[.]" MTD at p. 39. Without knowing which cases Defendant means, it is impossible to respond to this inadequately briefed assertion. Likely, however, Defendant means cases in which the *same* Plaintiffs file multiple lawsuits against the *same* Defendant in different forums. But here, as Defendant concedes, Plaintiffs only sued Zydus in this lawsuit.

Plaintiffs, of course, acknowledge that they are not entitled to a double recovery. *P. v. Portadin*, 432 A.2d 556, 560 (N.J. Super. Ct. App. Div. 1981). But

Defendant's remedy is to seek an offset if Plaintiffs recover from or settle with another manufacturer. The *Portadin* decision itself, one of two cases Defendant cites in this section of its brief, involved multiple defendants who caused the same injury. Nevertheless, the court did not order defendants dismissed; it simply cautioned the plaintiffs that they could not recover twice for the same injury. *Id.* When, as here, multiple manufacturers cause similar harm, but the court would not have jurisdiction over all of them, it makes no sense to limit Plaintiffs to a single lawsuit.

To the extent Defendant just means it would have been *simpler* if Plaintiffs had filed suit against all Amiodarone manufacturers in a single lawsuit, Plaintiffs agree. Plaintiffs attempted to do so in California. And rather than accepting personal jurisdiction to avoid wasting "this Court's resources as well as Zydus'" Zydus chose instead to contest personal jurisdiction. In light of the Supreme Court's decision in *Bristol-Myers Squibb Co. v. Superior Court* ("*BMS*"), 137 S. Ct. 1773 (2017)—which the Supreme Court decided while Plaintiffs' claims were pending in California—Zydus succeeded in its argument. So, as suggested by *BMS* itself, Plaintiffs filed suit in the manufacturers' home state. *See* 137 S. Ct. at 1783 ("Our straightforward application in this case of settled principles of personal jurisdiction will not result in the parade of horribles that respondents conjure up. . . . Our decision does not prevent the California and out-of-state plaintiffs from joining together in a consolidated action in the States that have general jurisdiction over BMS.").

Finally, contrary to Zydus' implication, it is black-letter law that a court need not add even "necessary" parties if it is not "feasible." FED. R. CIV. P. 19(a). "Joinder may not be feasible for a number of reasons, including . . . because the court lacks personal jurisdiction over the absentee." *Wilson v. Can. Life Assurance Co.*, No. 4:08-CV-1258, 2009 U.S. Dist. LEXIS 16714, at *7 (M.D. Pa. 2009). Here, Zydus does not even contend that the absent parties are "indispensable" or that the court would have jurisdiction over them—nor could it, in light of its successful attempt to prevent Plaintiffs from suing in a single case.

Despite, in California, urging Plaintiffs to sue it in New Jersey, Zydus now complains that it is somehow "gamesmanship" for Plaintiffs to do so. But because Zydus cites no authority showing that Plaintiffs' actions were improper, this Court should reject its argument.

VI. The Court Should Grant Leave to Amend.

Finally, if this Court concludes that any of Plaintiffs' allegations are insufficiently pleaded, it should allow Plaintiffs the ability to re-plead their claims based on the findings of the Court. *Ee Mullin v. Balicki*, 875 F.3d 140, 150 (3d Cir. 2017) ("While abuse of discretion is ordinarily a deferential standard of review, it has bite in this context; the District Court's discretion, circumscribed by the Rule 15's directive in favor of amendment, must be 'exercised within the context of liberal pleading rules.'") (internal citations omitted).

CONCLUSION

Plaintiffs ask this Court to deny the motion or grant them leave to amend.

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